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## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES LIMITED and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,

**Plaintiffs** 

VS.

TEVA PHARMACEUTICALS, USA, INC.

Defendant.

Civil Action No. 05-197 (GMS)

FILED UNDER SEAL

# TEVA'S MOTION IN LIMINE NO. 2 TO TO EXCLUDE EXPERT TESTIMONY BY PATENT ATTORNEY EGON BERG

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Dated: October 23, 2006

Teva Pharmaceuticals, USA, Inc. ("Teva") respectfully moves this Court *in limine* for an Order striking attorney Egon Berg's expert report and precluding GlaxoSmithKline ("GSK") from offering Mr. Berg's testimony at trial, as Mr. Berg seeks to provide opinion testimony on legal issues related to Teva's inequitable conduct claims.

#### **BACKGROUND**

As one of its defenses in this case, Teva contends that the patents-in-suit (the '808 and '860 patents) are unenforceable due to GSK's inequitable conduct during the prosecution of those patents. To respond to this defense, GSK served an expert report from an attorney, Mr. Egon Berg. Mr. Berg specializes in patent and trademark law. (Ex. A¹, 9/22/06 Berg Rep. ¶ 1.)

Mr. Berg's opinions are based on his understanding of case law, the Manual of Patent Examining Procedures, and "facts which [he has] been asked to assume as true." (*Id.* ¶¶ 30-31.) Among the materials Mr. Berg cites as considered in forming his opinions are more than forty Federal Circuit and other judicial decisions. (*Id.* Ex. B.)

With respect to both of the patents-in-suit, Mr. Berg opines, from his perspective as a patent attorney, on whether the "generic claims" provide a "basis for a finding of inequitable conduct." (Id. ¶ 9.) Mr. Berg also addresses whether "there is [a] basis for a finding of inequitable conduct . . . based on the information in the '808 patent specification concerning human dosage." (Id.) As stated in his report, Mr. Berg's ultimate opinion is that, with respect to the two patents-in-suit and the allegations on which he offers an opinion, "there is no basis for inequitable conduct." (Id. ¶ 10.)

All exhibits referenced herein are attached to the October 23, 2006 Declaration of Karen E. Keller filed concurrently herewith.

In discussing his views on the validity of what he characterizes as the "generic claims" in the '808 and '860 patents, Mr. Berg's report offers the explanation that "[a] genus or generic claim is one that covers more than a single chemical compound." (Id. ¶ 29.) According to Mr. Berg, a patent attorney's "duty of candor" does not preclude a patent practitioner from being "greedy" by "obtain[ing] the broadest generic claims possible." (Id. ¶ 27 & n.1.) He opines that "[t]he practice of obtaining generic claims . . . is consistent with . . . basic patent law principles, as I understand them." (Id. ¶ 29) (emphasis added). With respect to both patents, Mr. Berg opines, based on his expertise as a patent lawyer, that the scope of the claims is reasonable. (Id. ¶ 31, 38.) He states, for example, with respect to the '860 patent that "it is not inequitable conduct to seek claims as broad as possible taking into account the teachings of the specification and the prior art." (Id. ¶ 38.) (emphasis added) Mr. Berg states that "it is my opinion that there is no basis for a finding of inequitable conduct with respect to the scope of the generic claims." (Id. ¶ 9.) (emphasis added)

Mr. Berg also offers his opinion on Teva's inequitable conduct claim "that the '808 patent is invalid because [Teva] asserts that GSK misled the Patent Office into believing that it had already tested for an effective dose in humans." (*Id.* ¶ 39.) In his report, Mr. Berg states that his opinion in this context is based on his experience "as a patent attorney and patent examiner," as well as on the Manual of Patent Examining Procedures. (*Id.* ¶ 41.) Based on that legal experience, he states that a patent examiner would not have construed the dosage recommendation in the '808 patent claim as a misrepresentation of testing already completed. (*Id.* ¶ 41.) Mr. Berg opines that "there is no basis for concluding that there was any misrepresentation in the '808 patent with respect to dosage." (*Id.* ¶ 11.)

#### **ARGUMENT**

Mr. Berg, a lawyer, offers opinions on whether there is a "basis for a finding of inequitable conduct" based on his understanding of patent law, the proper scope of patent claims, and on the legal duty of candor. Such proffered testimony is nothing more than legal opinions that are irrelevant and unhelpful to determining whether GSK engaged in inequitable conduct. GSK should be precluded from offering such testimony at trial.

First, Mr. Berg's opinions should be stricken as improper legal testimony. Here, Mr. Berg is an attorney who bases his opinion on his experience as a patent attorney and on case law. Indeed, the very fact that Mr. Berg considered numerous Federal Circuit decisions in connection with forming his opinions on inequitable conduct (Berg Rep. Ex. B) shows why his proffered testimony should be improper. Moreover, Mr. Berg's opinions on the ultimate issue—i.e., whether GSK committed inequitable conduct in prosecuting the patents-in-suit—simply substitutes his judgment as attorney for that of the Court's. (Id. ¶¶ 9, 10, 38.) For these reasons, the courts in this jurisdiction and others routinely preclude such legal testimony and opinions. See, e.g., Proctor & Gamble Co. v. Teva Pharmaceuticals USA, Inc., 2006 WL 2241018, at \*1 (D. Del. Aug. 4, 2006) (Ex. B) ("This Court excludes testimony by patent law experts on substantive issues of patent law."); ONDEO Nalco Co. v. Eka Chem., Inc., 2003 WL 1524658, at \*3, \*6 (D. Del. Mar. 21, 2003) (Ex. C) (striking patent law expert's report and testimony concerning inequitable conduct); Revlon Consumer Prods. Corp. v. L'Oreal S.A., 1997 WL 158281, at \* 2-3 (D. Del. Mar. 26, 1997) (Ex. D) (holding that defendant's patent law expert "may not testify as to substantive issues of patent law, including inequitable conduct"); see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 1995 WL 261407, at 2-4 (N.D. Cal. Apr. 25, 1995) (Ex. E); W.R. Grace & Co. v. Viskase Corp., 1991 WL 2611647, at \*1 (N.D. Ill. Oct. 15, 1991) (Ex. F).

Second. to the extent Mr. Berg's proffered testimony is not legal in nature, it is irrelevant. Teva's inequitable conduct claim involves a factual inquiry into whether GSK made material misrepresentations with the intent to deceive the patent office during the prosecution of the '808 and '860 patents. See Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1384 (Fed. Cir. 2005); see also Impax Labs., Inc. v. Aventis Pharms., Inc., 333 F. Supp. 2d 265, 277 (D. Del. 2004). Mr. Berg's legal conclusions on the issue of inequitable conduct are based on "assumed facts" and "standard practices." Significantly, Mr. Berg is not, and does not purport to be, a technical expert in opining on the issues related to the sufficiency of the patent claims. Nor does Mr. Berg have any expertise in the intent of the applicants for the patents-in-suit. Accordingly, Mr. Berg's opinions outside his area of law are irrelevant and unhelpful to the factual inquiries related to inequitable conduct. For this reason as well, where the factual inquiries related to inequitable conduct are likewise the province of this Court as the trier of fact, Mr. Berg's proffered testimony should be stricken. See also Syngenta Seeds, Inc. v. Monsanto Co., 2004 WL 2106583, \*1 n.1 (D. Del. Sept. 8, 2004) (Ex. G) ("Of course, any claims of inequitable conduct will be presented in a bench trial, further obviating the need for legal experts.")

#### **CONCLUSION**

For the foregoing reasons, Teva respectfully requests that this Court strike Mr. Berg's expert report and preclude GSK from offering his testimony at trial.

Respectfully submitted,

#### /s/ Karen E. Keller

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Dated: October 23, 2006

#### CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on October 30, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

> Patricia Smink Rogowski, Esquire Connolly, Bove, Lodge & Hutz LLP The Nemours Building 1007 North Orange Street Wilmington, DE 19801

I further certify that on October 30, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and the following non-registered participant in the manner indicated:

#### BY E-MAIL ON OCTOBER 30, 2006 AND BY FEDERAL EXPRESS ON OCTOBER 31, 2006

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